

# 15

JRW  
6/12/03**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): Irvin et al.  
Appl. No.: 09/865,159  
Conf. No.: 3428  
Filed: May 24, 2001  
Title: PSEUDOMONAS TREATMENT COMPOSITION AND METHOD  
Art Unit: 1645  
Examiner: J. Graser  
Docket No.: 113190-64

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESPONSE TO OFFICE ACTION**

Sir:

This Response is submitted in response to the Office Action dated November 18, 2002.

**REMARKS**

In the Office Action, Claim 20 is rejected under 35 U.S.C. §112, first paragraph. The Patent Office asserts that the claimed invention with respect to SEQ ID Nos: 4, 8 or 10 is allowable. With respect to SEQ ID No: 6, however, the Patent Office questions as to whether Applicants were in possession of same as amended at the time of filing and thus in compliance with 35 U.S.C. §112. Applicants believe that this rejection is improper for at least the reasons set forth below.:

At the outset, the primary issue with respect to the rejection is whether the amendments made to the sequence listings and corresponding figures in Applicants previously-submitted Amendment (filed on August 12, 2002) added new matter. For example, Applicants amended SEQ ID No: 6 to correct the amino acid residue "Ser" with "Cys" at position 120. Applicants believe that this amendment did not add new matter and thus should be entered and examined.

SEQ ID No: 6 represents a polypeptide sequence of a modified pilin peptide pursuant to an embodiment of the claimed invention. This sequence is a truncated pilin peptide derived from the PAO strain. As further illustrated in Figure 1C, SEQ ID No: 5 represents the corresponding polynucleotide sequence. See, Specification, pages 7 and 15. One of the advantages of the present invention is to prevent self-assembly, i.e., oligomerization, by modifying the N terminus

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of the protein to prevent alpha helix formation thereby producing a pilin peptide in monomeric or dimeric form that can be effective to treat or prevent infection by *Pseudomonas aeruginosa*. See, Specification, page 6, lines 11-15.

The N-terminal portion can be modified by deletion (i.e., truncation), substitution or addition of amino acid residues effective to produce a non-self-assembling peptide that can be determined from known physical interactions that determine the properties of proteins, and from the conformational properties of polypeptide chains. In particular, modifications that affect the ability of the N-terminal portion to disrupt alpha-helix formation in the first N-terminal 30 amino acid region of the protein are generally considered to be pertinent. Introduction of Pro residues, in particular, in this segment of the protein can significantly disrupt the alpha-helix formation, but other residues that tend to destabilize alpha-helices can include, for example, groups of Gly, His or Asn. For example, a string of continuous Gly, His, or Asn residues, e.g., 3-5 residue string, can effectively prevent alpha helix formation, as can periodic Pro residues, e.g., every 5-7 residues. See, Specification, page 6, lines 23-33.

Fig. 1C illustrates an exemplary coding sequence for a modified pilin peptide with a truncated N-terminal region derived from the PAO strain as defined by SEQ ID Nos: 5 and 6 as discussed above according to an embodiment of the present invention. See, Specification, page 8, lines 4-11. However, Applicants' amendment to SEQ ID No: 6 as illustrated in Fig. 1C is directed to the C-terminal region of the PAO pilin peptide. As previously discussed, the amendment seeks to correct a single amino acid residue "Ser" with "Cys" at position 120. Clearly, one skilled in the art would understand that the C-terminal region of the claimed PAO pilin peptide as defined by SEQ ID No: 6 would remain intact and thus not modified as the N-terminal portion as supported in the Specification and discussed above.

Further, the C-terminal region of the PAO pilin peptide was well-documented and known in the art at the time of the present invention. For example, the C-terminal region of the PAO pilin peptide is illustrated in Figure 8 as disclosed in U.S. Patent No. 5,468,484 ("484"), a copy of which is disclosed in an Information Disclosure Statement enclosed herewith. In general, the C-terminal region includes two Cys and intervening amino acid residues representative of the *Pseudomonas aeruginosa* strain (e.g., PAO) from which the peptide is derived. Typically, the C-terminal region has a length that varies between 14 and 19 amino acid residues including the two Cys residues. See, '484 Patent, col. 3, lines 40-62. Indeed, one of the inventors of the '484

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Patent is also named as an inventor with respect to the above-referenced patent application. In view of same, one skilled in the art would recognize that SEQ ID No: 6 and the other previously-submitted amendments discussed above were clearly within the possession and knowledge of the inventors at the time the above-referenced application was filed. Therefore, Applicants, again, assert that the previously-submitted amendments did not add new matter, and thus are in compliance with 35 U.S.C. §112.

Accordingly, Applicants respectfully request that the rejection of Claim 20 be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

BELL, BOYD & LOYD LLC

BY 

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Dated: May 19, 2003

PTO/SB/30 (10/2001)

Approved for use through 10/31/2002 OMB 0651-0031

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# 14  
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6/17/03**REQUEST****FOR****CONTINUED EXAMINATION (RCE)  
TRANSMITTAL**

Address to:  
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 Box RCE  
 Washington, DC 20231

<i>Application Number</i>	09/865,156
<i>Filing Date</i>	May 24, 2001
<i>First Named Inventor</i>	Randell T. Irvin
<i>Art Unit</i>	1645
<i>Examiner Name</i>	J. Graser
<i>Attorney Docket Number</i>	113190-064

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application. Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

**1. Submission required under 37 CFR §1.114**

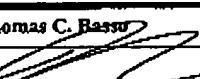
- a.  Previously submitted
  - i.  Consider the amendment(s)/reply under 37 CFR §1.116 previously filed on \_\_\_\_\_ (Any unentered amendment(s) referred to above will be entered).
  - ii.  Consider the arguments in the Appeal Brief or Reply Brief previously filed on \_\_\_\_\_
  - iii.  Other \_\_\_\_\_
- b.  Enclosed
  - i.  Amendment/Reply      iii.  Information Disclosure Statement (IDS)
  - ii.  Affidavit(s)/Declaration(s)      iv.  Other \_\_\_\_\_

**2. Miscellaneous**

- a.  Suspension of action on the above-identified application is requested under 37 CFR §1.103(c) for a period of \_\_\_\_\_ months (Period of suspension shall not exceed 3 months; Fee under 37 CFR §1.17(i) required)
- b.  Other \_\_\_\_\_
- 3. **Fees** The RCE fee under 37 CFR §1.17(e) is required by 37 CFR §1.114 when the RCE is filed.
- a.  The Director is hereby authorized to charge the following fees, or credit any overpayments, to Deposit Account No. 02-1818
  - i.  RCE fee required under 37 CFR §1.17(e)
  - ii.  Extension of time fee (37 CFR §§1.136 and 1.17)
  - iii.  Other Any additional fees \_\_\_\_\_
- b.  Check in the amount of \$ 840.00 enclosed
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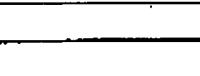
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**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED**

Name (Print / Type)	Thomas C. Bassur	Registration No. (Attorney / Agent)	46,541
Signature		Date	May 19, 2003

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I hereby certify that the following documents relating to the above-identified application:

1. Request for Continued Examination Transmittal (duplicate);
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3. Response to Office Action (3 pgs.);
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5. PTO Form 1449;
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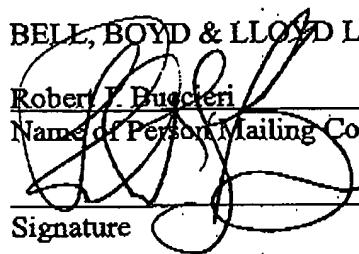
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Respectfully submitted,

BELL, BOYD & LLOYD LLC

  
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Robert J. Bucceri  
Name of Person Mailing Correspondence

\_\_\_\_\_  
Signature

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Phone Number 703-308-1742  
From Thomas C. Basso  
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**PSEUDOMONAS TREATMENT COMPOSITION AND****METHOD**

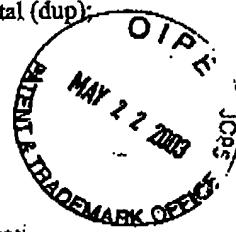
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**Docket No.: 113190-064**  
**USSN: 09/865,159**

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